EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., and ENDO PAR INNOVATION COMPANY, LLC *Plaintiffs,* v. ZYDUS PHARMACEUTICALS (USA) INC. and ZYDUS LIFESCIENCES LTD. *Defendants.*	C.A. No. 23-866-JLH-LDH

AMENDED JOINT CLAIM CONSTRUCTION CHART

Pursuant to the Court's Oral Order (D.I. 72), Plaintiffs Par Pharmaceutical, Inc., and Endo Par Innovation Company, LLC (collectively, "Plaintiffs" or "Par") and Defendants Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd. (collectively, "Defendants" or "Zydus") submit this Amended Joint Claim Construction Chart identifying the parties' agreed-upon constructions, the claim terms at issue for U.S. Patent Nos. 11,717,524 (the "'524 patent") and 11,779,587 (the "'587 patent") which remain in dispute, as well as a concise statement of what the parties' dispute is for each term. This Chart also articulates what Plaintiffs contend is the plain and ordinary meaning of each term where Plaintiffs indicate no construction is necessary and/or the term should be given its plain and ordinary meaning. A copy of the '524 and '587 patents (Exhibit A-B) and portions of the intrinsic record relied upon (Exhibits C - N) are attached to the Joint Claim Construction Chart (D.I. 58).

I. The Parties' Agreed-Upon Constructions

The parties agree on the construction of the following terms of the '524 patent claims:

Claim Term	Agreed Construction
"means for reducing the nitrosamine impurities" ('524 patent, claim 1)	"means for reducing the amounts of the nitrosamine impurities, wherein the amounts of nitrosamine impurities are decreased by the means" (For clarity, this construction does not require that there be a single means for reducing nitrosamine impurities.)
"means for removing the nitrosamine impurities" ('524 patent, claim 12)	"means for removing the nitrosamine impurities, wherein the nitrosamine impurities are removed by the means" (For clarity, this construction does not require that there be a single means for removing nitrosamine impurities or that the means remove all nitrosamine impurities.)
"employing an acid-base treatment to remove the nitrosamine impurities" ('524 patent, claims 18 and 26)	"employing an acid-base treatment to remove the nitrosamine impurities, wherein the nitrosamine impurities are removed by the acid-base treatment" (For clarity, this construction does not require that the acid-base treatment remove all nitrosamine impurities.)

II. Each Parties' Proposed Construction of Each Disputed Term of the '524 and '587 Patents

The parties dispute the construction of the following terms of the '524 and '587 claims:

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence	Concise Statement of the Parties' Dispute
"an acid-base treatment" ('524 patent, claims 1, 12, 18, and 26)	Indefinite To the extent the court requires a construction, "an acid-base treatment that extracts the varenicline product into the aqueous phase while leaving the nitrosamine impurities in the organic phase"	A POSA reading the specification and prosecution history would not, with reasonable certainty, be able to ascertain the meaning of the claim limitations reciting "an acid-base treatment." *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). The '524 patent. *See, e.g.*, '524 patent at claims; '524 patent at 13:16-25; 14:20-55; 15:58-17:17 and Table 3; Figs. 1 and 11; 21:10-52; 22:19-30; 37:53-42:35; 65:51-68:67 and Table 23. '824 application file history, Sept. 9, 2022, Claims; Jan. 18, 2023, Non-Final Rejection; Mar. 29, 2023, Amendment and Remarks; Apr. 17, 2023, Applicant-Initiated Interview	Not indefinite; plain and ordinary meaning The plain and ordinary meaning of the term "an acid-base treatment" refers to "a process to separate a desired substance from an undesired substance via treatment with an acid and subsequent treatment with a base."	Support is found at least at: '524 patent, claims 1, 6, 12, 13, 18, 20, 26, 13:16-25, 14:9-34, 15:58-16:16.	The parties dispute (1) whether the term "an acid-base treatment" is indefinite to a POSA, and (2) whether the term "an acid-base treatment" should be construed to require "an acid-base treatment that extracts the varenicline product into the aqueous phase while leaving the nitrosamine impurities in the organic phase."

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence	Concise Statement of the Parties' Dispute
		Summary; Apr. 18, 2023, Supplemental Amendment and Remarks; May 12, 2023, Final Rejection; May. 18, 2023, Amendment and Remarks; June 7, 2023, Notice of Allowability.			
"0.15% (w/w)" ('587 patent, claims 1, 13, and 24)	Indefinite To the extent the court requires a construction, "0.15% (w/w) of [impurity]/Varenicline Tartrate Maltodextrin premix (1:10)"	A POSA reading the specification and prosecution history would not, with reasonable certainty, be able to ascertain the meaning of the claim limitations reciting "0.15% (w/w)." *See Nautilus*, 572 U.S. at 910. The '587 patent. *See e.g.*, '587 patent at claims; '587 patent 2:6-42; 2:64-3:2; 3:3-8; Fig. 4, 5, 7; 7:15-34; 17:43-22:29; 23:10-12; 23:34-36; Table 5 (cols 29-32); 24:8-28; 35:34-37; 38:5-9; 50:16-24; 51:44-45; Table 14; 55:29-59:28; Tables 19-21; examples 1-5.	Not indefinite; Plain and ordinary meaning The plain and ordinary meaning of the term "0.15% (w/w)" refers to the weight of one substance divided by weight of another substance. In the context of claims 1 and 24, this means the weight of the claimed impurity divided by the weight of the varenicline tartrate tablet. In the context of claim 13, this means the weight of the claimed impurity	Support is found at least at: '587 patent, claims 1, 13, 24, and 28, 6:1-4, 14:55-65, 23:17-33, 24:8-28, 49:18-68:49,72:54-73:19. *See also, e.g.*, Chantix April 2010 Highlights of Prescribing Information for its Varenicline Tablets; Par's July 2021 Highlights of	The parties dispute (1) whether the term "0.15% (w/w)" is indefinite to a POSA, and (2) what is the correct denominator for this term.

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence	Concise Statement of the Parties' Dispute
			divided by the weight of the varenicline tartrate API in the claimed tablet.	Prescribing Information for its Varenicline Tablets; "Apo-Varenicline—varenicline tablet, film coated," Apotex Corp., Important Prescribing Information dated July 2, 2021; "Control of Nitrosamine Impurities in Human Drugs—Guidance for Industry", dated Sept. 2020; FDA "Liquid Chromatography-High Resolution Mass Spectrometry (LC-ESI-HRMS)	

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence	Concise Statement of the Parties' Dispute
				Method for the Determination of Varenicline Nitroso-Drug Substance Related Impurity (NDSRI) in Chantix™ Drug Product and Varenicline Drug Substance" dated August 6, 2021; "FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix)", dated July 30, 2021; "FDA Updates and Press Announcements on Nitrosamine in	

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence	Concise Statement of the Parties' Dispute
				Varenicline (Chantix)", dated May 5, 2022; ICH Harmonised Tripartite Guidelines, "Impurities in New Drug Substances Q3A(R2)"; "Assessment Report – Procedure under Article 5(3) of Regulation EC (No) 726/2004 – Nitrosamine impurities in human medicinal products," European Medicines Agency—Committee for Medicinal Products for Human Use	

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence	Concise Statement of the Parties' Dispute
				(CHMP), dated June 25, 2020; FDA "Laboratory analysis of varenicline products" dated Feb. 8, 2022. Support can also be found in the file history of the '587 patent, including the July 11, 2023 Amendment and Response to Non-Final Action. Par reserves the right to rely on this or any other portion of the '587 patent file history.	
"as measured by [method]" ('524 patent, claims 1 and	Should be construed similar to the "product-by-process	The '524 patent. *See e.g.*, '524 patent at claims; '524 patent at 2:1-6; 3:16-23; 3:43-46; 6:59-67; 9:35-61;	Not product-by-process claims.	Support is found at least at:	Par believes that the parties agree that the claim terms at issue are not product-by-process

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence	Concise Statement of the Parties' Dispute
18; '587 patent, claims 1, 13, and 24)	claims". *See* MPEP 2113 ("[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re*	11:66-12:21; 15:5-40; 20:1-21:9; 21:53-22:65; 46:35-63:37; Table 22. The '587 patent. *See e.g.*, '587 patent at claims; '587 patent at 2:1-5; 3:16-23; 3:43-46; 9:58-10:17; 12:24-51; 15:51-16:20; 21:10-22:29; 23:27-24:41; 49:19-68:50; Table 22. '824 application file history, Jan. 18, 2023, Non-Final Rejection. U.S. Application No. 18/148,659 ("the '659 application") prosecution history, Apr. 17, 2023, Non-Final Rejection.	The claims do not require the accused infringer to use the methods recited in the claims to measure the impurity.	'524 patent, claims 1 and 18; '587 patent claims 1, 13, and 24. '587 patent, 50:5-60:49 (and corresponding disclosure from '524 patent). *See also, e.g.*, FDA "Liquid Chromatography-High Resolution Mass Spectrometry (LC-ESI-HRMS) Method for the Determination of Varenicline Nitroso-Drug Substance Related Impurity (NDSRI) in Chantix™	claims and thus Par believes no further construction is necessary. Zydus believes that these terms should be construed similar to product-by-process claims and that the dispute is (1) whether the claims require that the claimed measurement technique be used to measure the impurity in the accused product for purposes of infringement, and (2) whether the prior art must disclose the claimed measurement technique for purposes of invalidity.

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence	Concise Statement of the Parties' Dispute
	Thorpe, 777 F.2d 695, 698 (Fed. Cir. 1985)) (citations omitted).			Drug Product and Varenicline Drug Substance" dated August 6, 2021	

Dated: June 14, 2024

FARNAN LLP

/s/
Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 North Market Street, 12th Floor
Wilmington, Delaware 19801
(302) 777-0300
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Plaintiffs

Respectfully submitted,

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/
Pilar G. Kraman (#5199)
Alexis N. Stombaugh (#6702)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
pkraman@ycst.com
astombaugh@ycst.com

Attorneys for Defendant Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited